

Notice of Allowability

Application No.

09/963,570

Examiner

Sharmila S. Gollamudi

Applicant(s)

KAI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/10/04.
2. ☒ The allowed claim(s) is/are 1,4,8,9,11 and 13-22.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted:
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ronald Kubovcik on December 10, 2004 and December 21, 2004.

The application has been amended as follows:

Please **cancel claim 7**.

In claim 8, after the word "dialysis" on line 6, add "; said solid preparation not containing sodium bicarbonate."

In claim 8, after the word "solution" on line 11, add "consisting of said sugar or a different sugar,". Also, delete "is dissolved" in lines 11-12.

Claim 8 should read as follows: A solid preparation for dialysis prepared by a process comprising: spraying an aqueous solution containing one more electrolytes selected from group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate onto core particles comprising particles sodium chloride to obtain first coated particles, and drying the first coated particles to obtain granules of first composition having an average particle diameter of 300 to 1,700 gm; spraying, onto core particles comprising particles sugar, an aqueous solution consisting of said sugar or a different sugar, ~~is dissolved~~ to obtain second coated particles, and drying the second coated particles to obtain granules of a second composition having an average

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particle diameter of 300 to 1,700 μm and which is about the same average particle diameter as the granules of the first composition; and mixing the granules of the first composition and the granules of the second composition, and mixing the resultant mixture with an acid to obtain a solid preparation for dialysis; said solid composition preparation not containing sodium bicarbonate.

In claim 9, after the word "dialysis" on line 5, add "; said solid preparation not containing sodium bicarbonate."

In claim 9, after the word "solution" on line 11, add "consisting of said sugar or a different sugar".

Claim 9 should read as follows: (currently amended) A solid preparation for dialysis prepared by a process comprising: spraying an aqueous solution containing one more electrolytes selected from the group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate onto core particles comprising particles of sodium chloride obtain first coated particles, and drying the particles to obtain granules of a first composition having an average particle diameter to 1,700 μm ; spraying, onto core particles comprising particles of a sugar, an aqueous solution consisting of said sugar or a different sugar of said sugar different sugar obtain second coated particles, and drying the second coated particles to obtain granules a second composition having an average particle diameter of 300 to 1,700 μm and which is about the same average particle diameter as the granules of the first composition; and mixing an acid with the granules of the first composition, and subsequently mixing the resultant mixture with the granules of the second composition to obtain a solid preparation for dialysis; said solid composition preparation not containing sodium bicarbonate.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The prior art of record does not disclose or fairly suggest exclusion of sodium bicarbonate from the dialysis composition or a composition wherein the electrolyte particles and the sugar particles are the same size to yield a homogeneous composition.

The instant claims are not rejected under Double Patenting over US patent 6,464,977 since US patent's solid preparation claims glucose particles that are coated with electrolytes and instant product excludes a coating on the glucose (sugar) particles with the instant claim language.

The rejection of instant claims under Double Patenting over US patent 6,407,070 and 6,489,301 are dropped since the instant claims exclude sodium bicarbonate in the composition and US patents require sodium bicarbonate in the solid preparation.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
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SSG


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